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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,302	03/18/2004	Wilhelmus Everardus Hennink	313632001120	7804

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,302	HENNINK ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 9-4-2007 has been entered. Claims 5 – 12 are pending pursuant to the amendment.

Priority

Applicants' argue that the instant Application is entitled to benefit of the 10/048,732 parent application. First, Applicants assert that the '732 application is identical to the WO 01/09198 PCT. The office has not confirmed this assertion, but it is deemed moot because benefit of the '732 application is still denied for the reasons of record and those discussed below.

The office first notes that for a parent application to support a claim continuation in part application, the parent must provide enabling support for the entire scope of the claim. The appropriate question is *not* whether the parent application envisioned the new claim; the appropriate question is whether the parent application describes how to make the invention claimed in the continuation in part application.

Applicants first note that the parent application explicitly states in several places that the polymers used therein are suitable for controlled release. However, the parent never actually shows or describes how to make a controlled release system from the polymers used in that Application. The prophetic statements in the parent regarding suitable uses of the polymers are merely an invitation to experiment, and do not teach the artisan how to make controlled release systems. Applicants further argue that homopolymers are supported because the parent specification states that when a polymer is references, copolymers are to be understood as included. Applicant goes on

to explain that while the parent Application preferred copolymers, homopolymers were not excluded. This argument is off the mark. The point is that that, regardless of what the parent application may have envisioned, it did not teach or show how to make instantly claimed controlled release system (nor any other drug-carrier system) from homopolymers of N-(2-hydroxypropyl) methacrylamide lactate. The systems taught by the parent are micelle-based systems, and the parent does not teach or show how to make such systems with the homopolymer. Indeed, it appears doubtful from the parent application whether the homopoymer is suitable for making micelles at all; because all of the micellular systems described in the parent are made with copolymers having a hydrophilic block such as PEG, the artisan would reasonably believe that such is required in order to form micelles (to the extent that added material in instant application may show this to be false, the added material is not considered for purposes of priority). With regard to Applicants' allegation that the copending application includes a description of copolymers with other than hydrophilic moieties such as PEG, the description of decomposition or degradation times of those polymers is not a description of how to make the invention using those polymers. From the parent application, it appears doubtful that such are actually useful in making micelles; applicants descriptions of such copolymers are merely invitations to experiment, and not enabling support. Furthermore, the parent Application clearly does not teach, or even envision, how to make the claimed controlled release system from alternating or random copolymers, both of which are included in "interpolymers" as recited in instant claim 1. Applicants' believe that the office is attempting to improperly limit the parent

applications' disclosure to its preferred embodiments. In response, the office is actually properly limiting the parent applications disclosure to what it actually teaches the artisan how to make and use, while disregarding prophetic statements, invitations to experiment, and technically useless generalizations.

Applicants' comments about ABA block copolymers appear to be correct upon further review. However, this is moot since the parent application still fails to teach the artisan how to make other elements of the claims (such as controlled release systems).

Claim Rejections - 35 USC § 112

Claims 5, 11, and 15 **remain** rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for micelle or hydrogel forming copolymers, does not reasonably provide enablement for homopolymers or copolymers that do not form micelles or hydrogels. This rejection is maintained for the reasons of record and those discussed below.

Applicant argues that paragraph 0072 of the instant application teaches how to make drug delivery systems from polymers that neither make micelles nor form hydrogels. This paragraph is reproduced below.

> **[0072]** The controlled release systems of the present invention can be prepared by the synthesis of a water soluble polymer. This is, *e.g.*, done by a) functionalizing a monomer with hydrolysable groups, b) mixing of said monomer with at least one monomer of a different type in a suitable ratio using a suitable solvent in the presence of an initiator and/or a catalyst to form said polymer c) removing said solvent and dissolving the polymer, and d) precipitating said polymer; in which process the functionalizing of the monomers of step a) is optionally carried out after step b) on the monomers as they are present in the polymer; and subsequently mixing said water soluble polymer with a releasable compound.

It is noted that this paragraph actually requires a copolymer. It requires that the monomer that has been functionalized with hydrolysable groups be mixed "with at least one monomer of a *different type* in a suitable ratio using a suitable solvent in the presence of an initiator and/or a catalyst to form said polymer..." (emphasis added). The use of two different types of monomers in the polymerization means that the resulting polymer will contain two different monomers and thus, by necessity, be a copolymer. This paragraph cannot teach the artisan how to do anything that does not involve a copolymer. Thus, the specification, even at the location cited by applicant, is not enabling for homopolymers.

Thus, the prior art becomes important, because that which is well known to the artisan need not be repeated in the Application itself. The art only recognizes that the polymers of the type claimed are useful for controlled release systems when they are micelles or hydrogels. The specification, as noted above, fails to teach otherwise. With respect to the need for a hydrophilic block, the fact that the specification does not note that this is required is noted. However, it is noted that the prior art of record, and sound scientific theory, recognizes that polymer micelles are formed from amphiphilic copolymers. Briefly, the scientific principle behind this is that in water the hydrophobic sections ("blocks") of multiple copolymer chains aggregate in a sphere-like shape in order to avoid exposure to water, thus forming a micelle. The specification does not teach how to make such micelles when there is no hydrophilic block. With respect to the allegation that the homopolymer becomes hydrophilic below the LCST, if this were true then the polymer would simply dissolve in water below the LCST. Hydrophilic

polymers (such as PEG, polyacrylate, polystyrene sulfonate, and others) dissolve in water, and do not form micelles or gels unless they are chemically or physically attached to a hydrophobic component.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 5, 8, 9, and 12 under 35 U.S.C. 102(a) as being anticipated by Cadee et al is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 103

Claims 5 – 7 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Neradovic et al. *Macromolecules* (2001) 34:7589-7591.

Claims 9 and 10 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Neradovic in view of US 5,939,543 to Heller.

Response to Arguments

Applicants arguments have been fully considered, but are not persuasive. Applicants' argue that Neradovic is not prior art, because Applicants believe that the claims are entitled to an effective filing date of 7/28/2000. However, as discussed above, Applicants are entitled only to the actual filing date of 3/18/2004, and therefore Neradovic is applicable as prior art under this statute.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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